

REMARKS

The present application is directed to therapeutic delivery compositions and methods that are particularly suited for the effective delivery of genetic matter and compounds to the interior of cells. Following entry of this amendment Claims 1-42 will be pending. No new matter is added and support for the amendments may be found throughout the specification and priority applications.

Priority

In the Office Action mailed December 1, 2004, the Examiner rejected applicants' priority claim to U.S.S.N. 08/138,271 (hereinafter the '271 application) and U.S.S.N. 07/673,289 (hereinafter the '289 application). Applicants respectfully traverse.

Applicants respectfully submit that U.S. Patent No. 2,674,619 to Lundsted discloses octablock copolymers. (See column 2, line 50-column 4, line 27 of the Lundsted patent). The use of ethylene diamine as base compound (Y) is specifically disclosed in Example 5 (column 11, lines 11-19). A copy of the Lundsted patent is enclosed for the Examiner's convenience. The Lundsted patent is clearly **incorporated by reference** in its entirety in the '271 application. (See page 15, lines 20-23; page 17, lines 12-18, of the '271 application). Therefore, applicants' claim of priority to the '271 application for disclosing octablock copolymers is valid.

In addition, both the '271 application (see page 21 and 23) and the '289 application (see page 23, lines 13-17) incorporate by reference the scientific article of Schmolka *et al.* (*J. Am. Oil Chemist Soc.* 54:110-116 (1977), hereinafter "Schmolka"). As acknowledged by the Examiner, Schmolka *et al.* teach the synthesis of block polymer non-ionic surfactants including the octablock copolymers shown in Figure 4. Applicants respectfully submit that they and others skilled in the art have relied upon Schmolka for the disclosure of octablock copolymers. Both U.S. Patent Nos. 6,440,743 and 5,656, 611 to Kabanov *et al.* were previously cited by the Examiner and are prior art of record. Applicants direct the Examiner to Formula XVII (column 13, line 21-column 14, line 12) of U.S. Patent No. 6,440,743, wherein an octablock copolymer is synthesized as directed by Schmolka *et al.* Similarly, Formula XVII (column 7, line 53-column

8, line 11) of U.S. 5,656,611 describes synthesis of an octablock copolymer as directed by Schmolka *et al.*

Applicants respectfully submit that non-patent publications such as the Schmolka *et al.* article may be incorporated by reference in accordance with MPEP §608.01(p) as evidenced by the Kabanov *et al.* patents. However, if the Examiner maintains that the teachings of Schmolka *et al.* constitute essential material that cannot be incorporated by reference, then applicants are willing to amend the specification of the present application to include the material incorporated by reference as permitted by MPEP §608.01(p).

Applicants respectfully submit that the present application discloses nucleic acid sequences in combination with octablock copolymers and therefore correctly claims priority for the currently claimed combination. Accordingly, applicants respectfully request a priority date of at least October 15, 1993.

Claim rejections under 35 U.S.C. § 102

In the Office Action mailed December 1, 2004, the Examiner rejected Claims 1-5, 8-13, 16-23, 26-31, 33-36, 38 and 41 as anticipated by U.S. 6,359,054 to Lemieux *et al.* (hereinafter “Lemieux *et al.*”) under 35 U.S.C 102(e). Applicants traverse the rejection.

Applicants respectfully submit that Lemieux *et al.* is an invalid 102(e) reference. As discussed above, the present application is entitled to a priority date of at least October 15, 1993. Therefore, applicants respectfully request withdrawal of the rejection under 35 U.S.C. 102(e).

Claim rejections under 35 U.S.C. § 103

In the Office Action mailed December 1, 2004, Claims 1, 6, 7, 9, 14, 15, 19, 24-25, 27, 32, and 37 were rejected under 35 U.S.C. 103(a) as obvious over Lemieux *et al.* in view of U.S. 5,674,911 to Emanuele *et al.* (hereinafter “Emanuele *et al.*”). Applicants respectfully traverse.

Applicants respectfully submit that Lemieux *et al.* and Emanuele *et al.* are not valid prior art references because they were both filed after the priority date of the present application as described above. Applicants respectfully submit that the priority of the present application of at

least October 15, 1993 overcomes the rejection under 35 U.S.C. 103(a) and request its withdrawal.

Claims 1, 2, 5, 8, 17-20, 23, 26 and 41 were rejected under 35 U.S.C. 103(a) as obvious over Pahlson *et al.* (*Acta Pathol. Microl. Immunol. Scand. B.* (1986)) (hereinafter “Pahlson *et al.*”) in view of Woodard *et al.* (Laboratory Animal Science (1989)) (hereinafter “Woodard *et al.*”). Applicants respectfully traverse the Examiner’s rejection.

Applicants respectfully submit that Pahlson *et al.* and Woodard *et al.* are not valid prior art references because they were both filed after the priority date of the present application as described above. Applicants respectfully submit that the priority of the present application of at least October 15, 1993 overcomes the rejection under 35 U.S.C. 103(a) and request its withdrawal.

Claims 3, 4, 9-13, 16, 21-22, 27-31, 33, 35-36 and 38 were rejected under 35 U.S.C. 103(a) as obvious over Pahlson *et al.* and Woodard *et al.* as applied to Claims 1, 2, 5, 8, 17-20, 23 and 26 above, and further in view of U.S. Patent No. 4,902,500 to Jansen *et al.* (hereinafter “Jansen *et al.*”). Applicants respectfully traverse the Examiner’s rejection.

Applicants respectfully submit that Pahlson *et al.*, Woodard *et al.*, and Jansen *et al.*, are not valid prior art references because they were both filed after the priority date of the present application as described above. Applicants respectfully submit that the priority of the present application of at least October 15, 1993 overcomes the rejection under 35 U.S.C. 103(a) and request its withdrawal.

Claims 1-5, 8-13, 16-18, 20-22, 28-30 and 34-36 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kabanov *et al.* (U.S. Patent, 5,656,611). Applicants respectfully traverse the Examiner’s rejection.

As described above, applicants submit that the present application is entitled to a priority date of at least October 15, 1993. As such, Kabanov *et al.* is not a valid prior art reference and cannot be used to establish a case of *prima facie* obviousness.

Claims 17, 39-40 and 42 were rejected under 35 U.S.C. 103(a) as obvious over Lemieux *et al.* Applicants respectfully traverse the rejection and repeat that Lemieux *et al.* is not a valid 35 U.S.C. 103(a) reference due to applicants' priority date of at least October 15, 1993.

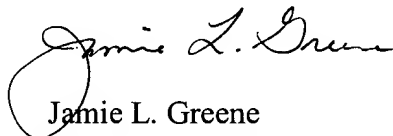
Accordingly, for the foregoing reasons, applicants respectfully request the withdrawal of the rejections under 35 U.S.C. §103.

CONCLUSION

The foregoing is submitted as a full and complete response to the Final Office Action mailed on December 1, 2004. No new matter is added by these amendments. For at least the reasons given above, applicants respectfully submit that the pending claims are novel and non-obvious. Accordingly, applicants submit that the claims in the present application are in condition for allowance, and such action is courteously solicited. No additional fees are believed due; however, the Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, to Deposit Account No. 11-0855.

The Examiner is invited and encouraged to contact the undersigned attorney of record at telephone number listed below if such contact will facilitate an efficient examination and allowance of the application.

Respectfully submitted,


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